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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/656,192

09/08/2003

Mark J. Cooper

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22907

7590

06/02/2006

BANNER & WITCOFF

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EXAMINER

LONG, SCOTT

ART UNIT

PAPER NUMBER

1633

DATE MAILED: 06/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/656,192	Applicant(s) COOPER ET AL.	
	Examiner Scott D. Long	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-123 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-123 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Species Elections

Three different species elections are required for examination of the invention described in application. *The applicant must choose one of each of the following: (1) Nucleic Acid type, (2) Polycation type, and (3) Counterion type.*

SPECIES 1 ELECTION: Nucleic Acid

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of Nucleic Acids for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-16, 18-19, 21-22, 24-62, 63-75, 76-82, 83-89, 90-96, and 97-123 are generic.

- A. cDNA, as recited in claim 17;
- B. antisense nucleic acid, as recited in claim 20;
- C. RNA, as recited in claim 23;

The species are distinct, each from the other because of the following reasons: The compound recited in species A, B, and C, above, are directed to products that have a separate status in the art in view of their different classification. Although all of the species of nucleic acids are composed of the same monomeric units, each molecule type has unique characteristics that cause them to have different classifications (class/subclass), search parameters and results, which would be non-overlapping.

SPECIES 2 ELECTION: Polylysine Polycations

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of Polylysine molecules with a cysteine residue Polycations for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-50, 52-62, 64-75, 77-82, 84-89, 91-96, and 102-123 are generic.

1. CK15-60P10, as recited in claim 51, 63, 76, 83, 90;
2. CK30P5, as recited in claim 97-101;
3. CK45P5, as recited in claim 97-101;

The species are distinct, each from the other because of the following reasons: The compounds recited in species 1, 2, and 3, above, are directed to products that have a separate status in the art in view of their distinct structure. Although all of the species of the molecules share generic chemical moieties, each species has unique structures and properties that cause them to have different effects on of nucleic acid condensation, which makes these species restrictable. Additionally, the applicant is reminded that a genus larger than the listed species, above, is claimed and presented in the specification. Species election is merely a method to narrow the initial search parameters of the invention.

SPECIES 3 ELECTION: Counterions

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of Counterions for prosecution on the merits to which the claims shall be restricted if no

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generic claim is finally held to be allowable. Currently, claims 1-7, 9-16, 18-19, 21-22, 24-25, 30-50, 52-62, 63-75, 77-82, 84-89, 91-96, and 102-123 are generic.

- i. acetate, as recited in claim 1, 8,17,20, 23, 26, 28, 51, 63, 76, 83, 90, and 97-101;
- ii. bicarbonate, as recited in claim 1, 8,17,20, 23, 26, 27, and 29 ;
- iii. chloride, as recited in claim 1, 8,17,20, 23, 27, 29 ;

The species are distinct, each from the other because of the following reasons: The compound recited in species i, ii, and iii, above, are directed to products that have a separate status in the art in view of their different classification. Each of the inorganic salts has unique characteristics that cause them to have different classifications (class/subclass), search parameters and results, which would be non-overlapping. Additionally, they have different effects on the condensation of nucleic acids. For these reasons, there is a substantial search burden to examine all of these together.

Applicant is required under 35 U.S.C. 121 to elect a single species for each of the three species groupings, above, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

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Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

The distinctions between the species of each of the three elections are noted above. Because these species are structurally distinct and because a search of one does not necessarily overlap with that of another species, it would be unduly burdensome for the examiner to search and examine all of the subject matter being sought in the presently pending claims, and thus, restriction/species election for examination purposes as indicated is proper.

Response Requirement

Applicant is advised that the reply to this requirement to be complete must include (i) an election of an invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Multiple Inventors

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Examiner Contact Information

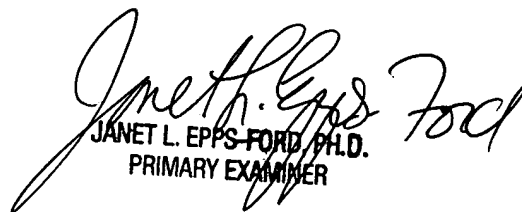
Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Scott Long** whose telephone number is **571-272-9048**. The examiner can normally be reached on Monday - Friday, 9am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Dave Nguyen** can be reached on **571-272-0731**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Scott Long
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JANET L. EPPS-FORD, PH.D.
PRIMARY EXAMINER